

OCT 1 0 2000

510(K) SUMMARY
(as required by 807.92 9c))

K002152

Submitter of 510(K): Regulatory & Marketing Service, Inc. (RMS)
3234 Ella Lane
New Port Richey, Florida 34655

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Art Ward

Date of Summary:

Trade Name: TRACK 1.0mm & 1.5mm Systems – Tissue Regeneration
by Alveolar Callus Distraction

Classification Name:

Predicate Device: K983515 – KLS-Martin Intraoral Vertical Distractor
K981526 – Ace Alveolar Distractor
K973484 – Chin Distractor

**Device Description/
Comparison:**

The TRACK distractors are designed to provide temporary stabilization and gradual expansion across an osteotomy in maxillomandibular skeleton and thereby increasing the height of the adjacent Alveolar ridge. This device is intended to be removed after consolidation of the callus and prior to final prosthetic reconstruction. The mechanism to achieve distraction is a threaded titanium rod with attached titanium plates, which are fixed to the mandible, or maxilla with titanium bone screws.

Intended Use:

The KLS-Martin TRACK distractors are intended for use in patients who have totally or partially edentulous mandible or maxilla or small craniofacial bone deficiencies and need an increase in bone height and mass by means of distraction osteogenesis. These patients include those who have traumatic defects, periodontal disease or birth abnormality. The TRACK distractors are designed to provide temporary stabilization and gradual expansion across an osteotomy in the mandibular bone or maxillary bone and thereby increasing the height of the adjacent Alveolar ridge. This device is intended to be removed after consolidation of the callus and prior to final prosthetic reconstruction. The mechanism to achieve distraction is a threaded titanium rod with attached titanium plates, which are fixed to the mandible, or maxilla with titanium bone screws.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2000

KLS-Martin L.P.
Mr. Arthur Ward
Regulatory Specialist
Regulatory & Marketing Services, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

Re: K002152
Trade Name: KLS Martin Track Distractor
Regulatory Class: II
Product Code: MQN
Dated: June 27, 2000
Received: July 17, 2000

Dear Mr. Ward:

This letter corrects our substantially equivalent letter of June 27, 2000 regarding the device name.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your

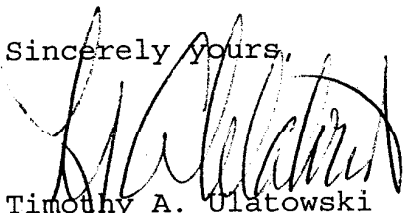
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premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note that the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 002152

Device Name: Zurich Pediatric Maxillary Distractor

Indications For Use:

The KLS-Martin TRACK distractors are intended for use in patients who have totally or partially edentulous mandible or maxilla or small craniofacial bone deficiencies and need an increase in bone height and mass by means of distraction osteogenesis. These patients include those who have traumatic defects, periodontal disease or birth abnormality. The TRACK distractors are designed to provide temporary stabilization and gradual expansion across an osteotomy in the mandibular bone or maxillary bone and thereby increasing the height of the adjacent Alveolar ridge. This device is intended to be removed after consolidation of the callus and prior to final prosthetic reconstruction. The mechanism to achieve distraction is a threaded titanium rod with attached titanium plates, which are fixed to the mandible, or maxilla with titanium bone screws.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801-109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

Suzanne P. Paves
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002152